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10/665,394	09/17/2003	Kurt-Reiner Geiss	7390-X03-018	4213

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Fleit Gibbons Gutman Bongini & Bianco PL  
21355 EAST DIXIE HIGHWAY  
SUITE 115  
MIAMI, FL 33180

EXAMINER

MAEWALL, SNIGDEHA

ART UNIT

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1612

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/665,394

**Applicant(s)**

GEISS, KURT-REINER

**Examiner**

Snigdha Maewall

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-850)  
Paper No(s)/Mail Date 01/05/09 and 01/07/09
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### Summary

1. Receipt of Applicant's arguments/Remarks, amended claims and **RCE** filed on 01/19/09 is acknowledged.

Receipt of IDS filed on 01/25/09 and 01/07/09 is also acknowledged.

Amendments to the specification in changing the title to "FOOD PRODUCT FOR IMPROVING COGNITIVE FUNCTIONAL CAPACITY" has been entered.

Claims 1-13 have been cancelled. New claims **14-36** have been presented in this application.

The rejections/objections not reiterated herein have been withdrawn in view of applicants arguments.

### *Claim Objections*

Claims 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 23 recites a limitation of combination including a minimum of **100 mg to about 300 mg** of phosphatidyl serine which is not further limiting the amount claimed in claim 16 as in an amount of 200-300 mg.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 14-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchholz et al. (US Patent No. 6,514,973) in view of Lang et al. (US Pub. No. 2003/0161861 A1).

Buchholz et al. discloses that the oral supplementation with 200 to 300 mg of phosphatidylserines per day for 2 to 6 months improves brain metabolism and benefits cognitive functions such as memory, thinking, learning, and the ability to concentrate especially in aging people and in patients with certain neurological and pathopsychological conditions (see column 2, lines 20-32).

The reference also discloses the effectiveness of phosphatidylserines in the treatment of senile dementia, Parkinson's disease epilepsy, depression, and age-associated memory impairment has also been demonstrated in several studies. (See column 2, lines 27-30). Buchholz et al. further teach that phosphatidyl serine provides metabolic support to a wide range of brain functions. Phosphatidyl serine stimulates glucose metabolism in the brain and also increases the number of neurotransmitter receptor sites. (See column 2, lines 32-35). Buchholz et al. discloses that the disclosed

compound (which includes phosphatidyl serine) is suitable for food or food supplement composition (see column 6, lines 55-56). The invention also relates to food or food supplement compositions comprising one or more active ingredients according to claim 1. (It is to be noted that claim 1 comprises phosphatidyl serine).

The reference further discloses that food compositions comprise one or more active ingredients and one or more nutritional substances. The nutritional substances encompass all materials which are suited for consumption both by animals and/or by human beings, e.g. vitamins and provitamins thereof, fats, minerals or amino acids. Nutritional substances, which can be part of the inventive food compositions are e.g. materials, which are derived substantially from a single natural source such as sugar, unsweetened juice, nectar or puree from a single species of plant, such as unsweetened apple juice (including a blend of different varieties of apple juice), grapefruit juice, orange juice, apple sauce, apricot nectar, tomato juice, tomato sauce, tomato puree, grain plants of a single species and materials produced from grain plants of a single species, such as corn syrup, rye flour, wheat flour or oat bran.

The food compositions are e.g. of food preparations such as breakfast foods, e.g. prepared cereals, toaster pastries, and breakfast drink mixes, infant formulas, dietary supplements, complete diet formulas, and weight-loss preparations, such as weight-loss drinks and weight-loss bars. The nutritional substances include all edible combinations of carbohydrates, lipids, proteins, inorganic elements, trace elements, vitamins, water, and active metabolites of plants and animals. (see column 5, lines 40-65 and column 6, lines 9-13). Buchholz et al. further teach that the specific dose of food or food

supplement for each patient depends on a wide variety of factors, for example on the activity of the specific compounds employed, on the age, bodyweight, general state of health, sex, on the diet, the time and route of administration (see column 6, lines 45-50).

Although Buchholz et al. teach that phosphatidyl serine stimulates glucose metabolism in the brain and also increases the number of neurotransmitter receptor sites. (See column 2, lines 32-35), Buchholz et al. do not explicitly teach role of carbohydrate in improving cognitive function of brain.

Lang et al. discloses a cereal product comprising starch, which improves cognitive performances, in particular memory retention, attention concentration, vigilance and /or mental well being in people and particularly in a child and an adolescent. Table 1 on page 2 discloses a composition comprising spaghetti, kidney beans potatoes white bread and whole meal bread etc. Table 8 depicts carbohydrates, proteins and lipids.

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate carbohydrates in the reference of Buchholz et al. since Lang et al. teach that food products containing carbohydrates such as starch improve cognitive performances. One skilled in the art would have been motivated to incorporate starch in the teachings of Buchholz because Buchholz teaches that Phosphatidyl serine stimulates glucose metabolism in the brain and also increases the number of neurotransmitter receptor sites. (See column 2, lines 32-35) and Lang et al. teaches that starch improves cognitive performances. Since starch is known to breakdown into glucose during metabolism, one skilled in the art would have reasonable

expectation of success in combining starch as taught by Lang et al. and phosphatidylserine as taught by Buchholz et al. in improving cognitive performances.

With respect to various amounts and percentages of various components, it is the position of the examiner that optimization of such parameters would have been within the purview of a skilled artisan at the time the invention was made by doing experimental manipulations in the absence of superior and unexpected results. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955).

#### ***Response to Arguments***

4. Applicant's arguments filed 12/19/08 have been fully considered but they are not persuasive.

Applicant argues that Buchholz does not teach the role of carbohydrates in improving cognitive function and no correlation has been disclosed between phosphatidyl serine and glucose.

Applicant's arguments are not persuasive because Buchholz teaches phosphatidyl serine increases glucose metabolism and secondary reference teaches starch in improving cognitive performances.

Applicant argues that Lang discloses that some studies improve cognitive performance whereas some do not. This argument is not persuasive because the reference's teachings are taken as whole and because the reference teaches some

carbohydrates do not increase cognitive performance, does not negate the fact that carbohydrates do increase cognitive performance. Manipulation of amount in order to achieve best possible results would have been within the purview of a skilled artisan at the time of instant invention.

Applicant argues that Lang does not teach phosphatidyl serine. In response to this argument, the examiner respectfully states that Lang was not cited for phosphatidyl serine, Buchholz was cited for phosphatidyl serine. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that in view of declaration, the combination of the two prior art would not have provided unexpected results. Applicant's arguments are not persuasive and response to declaration has been presented below.

#### ***Response to Declaration***

5. The declaration under 37 CFR 1.132 filed 12/19/08 is insufficient to overcome the rejection of claims 14-36 based upon the rejections as set forth in the last Office action because:

Applicant argues that:

Evidence of a greater than expected result may be shown by demonstrating an elect which is greater than the sum of each of the effects taken separately (i. e. demonstrating ~synergism").  
*Merck & Co. inc. v. Biocrq/t Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843



(Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). MPEP 716.02(a). Applicant demonstrated a greater than expected increase in cognitive functional capacity after consumption of a combination of phosphatidyl serine and simple carbohydrates over consumption of phosphatidyl serine or simple carbohydrates alone (shown in the second example). A schematic representation of ball flight is shown in Figure 2 of example two. After the first test, the golfers consumed a combination of 200mg phosphatidyl serine and 20g of simple carbohydrates (as IQPLUS Golf Bar, n=10), 20g of simple carbohydrates (as a nutrition bar, n=10), or 200mg of phosphatidyl serine (as soft gel capsules, n=2) for six weeks. After six weeks, the ball flight test was repeated, it was found that the combination of phosphatidyl serine and simple carbohydrates resulted in a significant improvement of good ball flights, whereas simple carbohydrate or phosphatidyl serine consumption did not improve performance. See "results" section of experimental example two for pre-test and post-test statistical comparisons. The improvements are known to be due to mental aspects, in light of the conditions of the experiment, i.e. the physical, mental, and golf-specific training habits of each individual participant remained unchanged during the supplementation phase. Thus, Applicant has provided evidence of a synergistic effect on cognitive functional capacity from the combination of phosphatidyl serine and simple carbohydrates over the effect of each ingredient alone (i.e. phosphatidyl serine alone and simple carbohydrates alone.....).

carbohydrates. Furthermore, the prior art does not teach a food, which after consumption, produces a marked increase in glucose uptake in the brain with concomitant beneficial results in cognitive function. One would not have any reason or motivation for incorporating carbohydrates into the composition of Buchholz because neither Lang nor other prior art suggests that carbohydrates combined with phosphatidyl serine can increase glucose uptake in the brain to improve cognitive functional capacity.

Applicant's arguments are not persuasive because of several reasons as discussed below:

The declaration contains only 200 mg of phosphatidyl serine and 20 g of carbohydrate whereas the claims as recited requires the limitation of minimum of 100 mg of phosphatidyl serine and minimum of 15 g of carbohydrate, as such no data has been provided for amounts which are below 200 mg of phosphatidyl serine and less

than 20 g of carbohydrate. Since the claims do not define specific range of amounts of various components and any specific carbohydrate, the scope of the claims do not commensurate with the scope of declaration. The declaration does not provide any cognitive performance for amount such as 100 mg of phosphatidyl serine or 15 g of carbohydrate.

Applicant consistently argues synergic affect of phosphatidyl serine and carbohydrate, however, review of table 3, does not show any difference between pre and post carbohydrate levels. By definition, the synergic affect means that there is some affect associated with the compound by itself, however the graph shows two equal bars for carbohydrate as such applicant's argument about synergistic affect is not persuasive.

The claims do not recite the synergic effect for phosphatidyl serine and carbohydrate, as such the scope of claims do not commensurate with the scope of declaration.

Review of the graph on page 7 of declaration shows standard deviation which is so high that one cannot determine the statistical significance let alone the palatable significance. The results do not appear to show even **an additive effect**.

Furthermore, Applicant has not provided the data with respect to various other food that the person under examination has consumed. what food in addition to the bar was consumed by subject population, did they consume no carbohydrate or did they consume eggs, since eggs have phosphatidyl serine in them. Therefore, in the absence

of substantial statistical results and incomplete data, it is the position of the examiner that the declaration is insufficient to overcome the rejection.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

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/Gollamudi S Kishore /

Primary Examiner, Art Unit 1612